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In-Home Obesity Prevention in Low-Income Infants Through Maternal and Social Transmission

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Abstract

Background—Extant obesity efforts have had a limited impact among low-income underserved children, in part because existing programs are limited in terms of their short duration and low dosage, limited accessibility and sustainability; and failure to address barriers faced by diverse low-income families.

Methods—This two-arm, parallel, randomized controlled trial (RCT) tests whether delivering obesity prevention, as part of an ongoing home visitation program (HVP), is an effective approach for primary (infants) and secondary (mothers) obesity prevention among low-income, underserved

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Authors' Contributions

Drs. Salvy and de la Haye designed the study and the intervention content and wrote the first draft of the manuscript. Dr. Chou helped to design the analytic plan and will oversee the data analysis in collaboration with Drs. Salvy and de la Haye. Drs. Chandler-Laney, Goran and Galama are co-investigators on the project, and they have critically reviewed the manuscript. All authors read and approved the final manuscript.

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Competing Interest Statement

The authors declare that they have no conflict of interest or competing interests pertinent to this study. The authors have no financial relationships relevant to this article to disclose.

Trial Registration

The study is registered with [ClinicalTrials.gov](https://clinicaltrials.gov) (Protocol Record NCT03529695).

Ethics Approval and Consent to Participate

The study protocol has been reviewed and approved by the University of Alabama at Birmingham Institutional Review Board (Proposal #RB-300001382) and by the University of Southern California Institutional Review Board (Proposal #HS-18-00025). Participants (mothers) will be required to provide informed written consent for themselves and their children before participating.

Consent for Publication

Not applicable.

Availability of Data and Material

The datasets from this study will be available from the principal investigators, Drs. de la Haye and Salvy, on written request.

families. This RCT further examines the role of maternal and social factors as key mechanisms of transmission of infants' obesity risk, and the real-life costs of delivering obesity prevention as part of HVPs. Specifically, 300 low-income mothers/infants (6mo at baseline) participating in the Healthy Families America home visitation program in Antelope Valley (CA) will be recruited and enrolled in the study. Home visitors serving families will be randomly assigned to deliver the standard HVP curriculum with or without obesity prevention as part of their weekly home visits for two years. Anthropometric, metabolic and behavioral assessments of mothers/infants will be conducted at enrollment and after 6 and 18 months of intervention.

Discussion—This study addresses the need to develop interventions targeting at-risk infants before they become obese. The proposed research is timely as the Institute of Medicine, the United States Department of Agriculture, and the Department of Health and Human Services are revising their recommendations to address key factors influencing obesity risk in children from birth to 24 months of age.

1. Introduction

Over 500 publicly and privately funded home visitation programs (HVPs) provide services to more than 650,000 low-income, underserved children and their families in the U.S. annually. HVPs are embedded in a comprehensive system of child and maternal health services that is designed to promote optimal child development and prevent adverse outcomes [1–5]. Randomized controlled trials (RCTs) show that high-quality HVPs can effectively improve children's physical and psychosocial health, such as, birth outcomes, breastfeeding, immunization rates, and overall cognitive and social development [5–23]. Although some HVPs provide basic information on infant nutrition, there has been no comprehensive and sustainable effort to address childhood obesity prevention, nutrition, and physical activity, as part of HVPs services. This is surprising as more than 40% of low-income children enrolled in federally-funded preventative programs are overweight or obese by age five [24–27]. Initiating and maintaining healthy habits is very difficult, especially for families that face a multitude of barriers, such as, poverty, housing instability, food insecurity, and a lack of access to linguistically and culturally competent services. These challenges highlight the need to integrate obesity prevention as an essential component of child and maternal health services.

Consistent with a capacity building approach, the proposed two-arm, parallel, randomized controlled trial (RCT) aims to test whether extending the curriculum and mission of HVPs can address obesity and health disparities. Specifically, this RCT tests whether delivering in-home obesity prevention as part of HVPs is an effective and sustainable approach for primary (infants) and secondary (mothers) obesity prevention among low-income, underserved families.

The RCT also focuses on understanding maternal and social determinants of intervention effects and identifying key determinants that can be leveraged to prevent childhood obesity in infancy. The intervention is based on the premise that maternal factors (maternal weight, feeding practices and home environment), and social network factors (supportive family and community social networks), are key pathways affecting child outcomes during the

important developmental period of infancy/early childhood. Accordingly, the intervention explicitly targets maternal health behavior and feeding practices [28–31], as well as mothers' social networks (i.e., their connections to people and organizations) by creating opportunities for meaningful, health-supportive relationships to be fostered and maintained (Figure 1).

The proposed study also includes a pragmatic economic analysis (costs, cost-savings, and non-monetary benefits) of integrating obesity prevention for infants into existing HVPs. The results can inform maternal and child health public policy initiatives that seek to address the intergenerational transmission of obesity and obesity disparities and prevent obesity in early childhood.

2. Methods

2.1. Overview of study design

Table 1 depicts the logic model underlying the proposed study. Healthy Families America home visitors (see 2.3. Intervention Arms) will be randomized to deliver the HVP curriculum with or without obesity prevention for 18 months (standard duration of services provided by our partner). Mothers and their infants will be recruited and enrolled on a rolling basis over 24 months, and matched to a home visitor based on race, ethnicity and language preference. Assessment of mothers and infants will be conducted by assessment workers (blind to study assignment) at enrollment, and after receiving 6 and 18 months of services.

The study protocol has been reviewed and approved by the University of Alabama at Birmingham Institutional Review Board (Proposal #RB-300001382) and by the University of Southern California Institutional Review Board (Proposal #HS-18-00025). Participants (mothers) will be required to provide informed written consent for themselves and their children before participating. The study will be reported according to the Consolidated Standards of Reporting Trials (CONSORT) statement [32], and is registered with [ClinicalTrials.gov](https://clinicaltrials.gov) (Protocol Record NCT03529695).

2.2. Participant recruitment and eligibility criteria

Participants will be low-income mothers and their infants (2 to 6 months at enrollment) who are already receiving services from our HVP community partner (Figure 2). Mothers are initially enrolled into the HVP through outreach and screening pre-partum, in English or Spanish, at community health centers and hospitals. In order to be eligible for the HVP mothers must meet a number of risk criteria such as poverty, housing instability, lack of social and material support, lack of transportation and limited education and literacy. Enrolled mothers are matched to a home visitor based on culture and language. Based on our formative work with our HVP partner, we expect to recruit 70% Hispanic/Latino, 13% African American, 8% White, 5% American Indian/Alaskan, 4% mixed race. Mothers/infants will be ineligible for the research study if they have any of the following conditions: eating disorders (e.g., bulimia nervosa), schizophrenia, and obesity-related syndrome (e.g.,

Prader Willi). Participants enrolled in a weight-loss program will be ineligible. Eligibility will be assessed via medical history as described in the 2.4. Measurements section below.

2.2.1. Recruitment and enrollment.—Assessment workers, who are employed by our community partner but are distinct from home visitors delivering services, will introduce the study to mothers and obtain written consent. They will clarify with mothers that their refusal to participate in the study will not affect their receipt of any other services provided by the HVP or community organization.

2.2.2. Randomization.—Randomization will be at the level of home visitors, who deliver the HVP to participating families (cluster randomization). Home visitors employed by our community partner will be randomly assigned to deliver either HVP only or HVP+ obesity prevention, stratifying by language of service delivery (Spanish/English) and case load (part time/full time). Potential concerns with randomizing by home visitors are feasibly addressed in this study. First, the likelihood of bias is reduced due to the homogenous population enrolled in HVPs (e.g., income, ethnicity/race). Second, to reduce contamination, the training and supervisions of home visitors assigned to each arm will be held on separate days. All analyses will control for home visitor work experience (number of years providing services).

2.3. Intervention Arms

2.3.1. Standard home visitation curriculum.—Our partner HVP is one of 400 nationwide *Healthy Families America* (HFA) sites/chapters, housed at Antelope Valley Partners for Health. The HFA model meets the DHHS criteria for an “evidence-based early childhood home visiting service delivery model” (See <http://homvee.acf.hhs.gov>). HFA services begin prenatally and continue until children are 2-5yo depending on the HVP model. The curriculum focuses on strengthening parent-child relationships and family functioning, promoting positive child development, and linkage to community resources (e.g., medical providers, financial/housing assistance, childcare, substance abuse treatment, community programs). HFA accredited home visitors (experienced Licensed Vocational Nurses or nurses) are matched to families on cultural background and language (English or Spanish), to provide culturally sensitive services. Home visitors are selected because of their personal characteristics (e.g., non-judgmental, compassionate, ability to establish a trusting relationship), their experience working with culturally diverse communities, and their skills to do the job.

2.3.1.1. Standard home visitation curriculum training. HFA home visitors receive rigorous training in handling situations encountered while working with at-risk families. They further receive training in cultural competency, substance abuse, reporting child abuse, domestic violence, and linkage to services in their community. Home visiting staff also receive intensive training specific to their role (e.g., identifying at-risk families, standardized assessments, phlebotomy, mental health referrals, promoting preventive health care, utilizing creative outreach efforts, establishing and maintaining trust with families, building upon family strengths, developing individual family support plans, teaching parent-child interaction, managing crises). Home visiting staff receive weekly supervision, ongoing

developmental training, and have limited caseloads (10-15 families) to meet their families' needs.

2.3.2. Obesity prevention curriculum (Table 3).—Our obesity prevention curriculum uses a culturally sensitive, language specific, and community-forming model of implementation to deliver key maternal and child nutrition and physical activity components as part of home visiting services in a way that is engaging for families. As is standard practice with home visiting services and family-centered obesity interventions, the home visitors engage other household members whenever possible (e.g., spouse; mother in law; grandparents).

Our formative work indicates that a mix of didactic and experiential approaches is needed to help families adopt behaviors that will promote their child's health. *Didactic education* focuses on in-home individualized coaching to help mothers implement changes in their "natural environment". A strong emphasis is placed on parent modeling healthy behaviors (i.e., co-engaging in healthy behaviors with their children) and goal setting in which mothers set weekly activity and nutrition goals (e.g., decreasing by "x" the number of sugar-sweetened beverages). Parents are taught strategies to change cues in their home environment to gradually eliminate high-energy dense foods from the home environment and make their home more conducive to exercising (e.g., removing computer/televisions from sleeping areas) [50].

The curriculum also includes *social experiential activities* premised on our theoretical framework that emphasizes social network influences. Mothers will be invited to participate in bimonthly group-led nutrition and physical activity communal classes and activities. These activities will be housed in our home visiting partner's facilities, which include meeting rooms and a demonstration kitchen. The goal of the communal classes and group activities is to twofold: 1) foster the development of relationships between mothers to create healthy social networks that are supportive of the newly developed healthy behaviors, and 2) provide the opportunity to engage in hands-on practice of the healthy eating and physical activity skills covered during the individual home visits. For example, during a communal cooking class, mothers will form small groups and collaboratively work on a quick and easy dish. A community health specialist will supervise the activities and facilitate discussion between participants. At the conclusion of the class, the small groups will reconvene in a larger group, and mothers will share their meals, which will also provide a communal context for discussion and exchange around shared experience. Childcare will be provided in an adjacent room to promote attendance. These social activities are akin to those delivered as part of the National Institute of Food and Agriculture's Expanded Food and Nutrition Education Program [51]. Home visitors delivering the obesity prevention curriculum will be asked to encourage mothers to attend the voluntary communal classes. We will also monitor the number of classes and group activities mothers attend to evaluate if participation in these activities is related to intervention outcomes.

2.3.2.1. Obesity prevention curriculum training.: Home visitors delivering the obesity prevention module receive a 2-day initial training and annual refresher courses, which covers (1) the importance of, rationale for, and education about the healthy behaviors targeted,

including addressing possible misinformation (e.g., recognizing starchy vegetables), and (2) practical advice specific to each targeted behavior (e.g., strategies to replace sugar-sweetened beverages and juices; ways to increase daily steps). Home visitors are trained to adapt the material to families' cultural and individual practices and preferences (e.g., food modifications based on favorite meals; selection of relevant/tailored cues).

2.3.3. Intervention fidelity.—Intervention fidelity encompasses integrity (intervention arms are implemented according to established procedures) and differentiation (intervention arms are distinct from one another) [52]. The following strategies and safeguards are used to ensure the fidelity of the intervention delivery: (1) Comprehensive assessment of the standard home visitation curriculum avoids content overlap between intervention arms. (2) As described in sections 2.3.1.1. Standard home visitation curriculum training, home visitors receive extensive training to master the standard home visitation program's psychosocial and educational curriculum (supported by scripted manuals) and they receive weekly supervision. The training, scripted manuals and supervision prevent drifting (i.e., avoid covering topics/areas not included in the standard curriculum). (3) Home visitors delivering the nutrition and physical activity curriculum receive a 2-day initial training and refresher courses, as described in section 2.3.2.1. Obesity prevention curriculum training. Implementation quality is further supported by a scripted obesity prevention manual and by weekly supervision to review progress, dosage and timing of delivery, and to provide the opportunity to resolve problems or issues encountered. (4) Interventions are delivered in the families' homes, and supervisions with home visitors implementing different arms are held on separate days to minimize the risks of contamination between the intervention arms. (5) Completion of checklists after each visit. After each visit, all home visitors have to complete a detailed checklist documenting the details of their visit (e.g., time spent in the home, topics discussed, problems encountered, parenting issues and challenges addressed) to comply with the requirements of the standard home visitation program model of implementation. All home visitors also have to carefully document the number of visits provided, and the reasons for visits missed or rescheduled. Home visitors implementing the obesity prevention curriculum will be required to complete an additional checklist to document the time spent discussing the obesity prevention curriculum as well as the specific nutrition and activity topics covered.

2.4. Measurements

Assessment workers (certified in phlebotomy) employed by our community partner will be trained to recruit families for the study and administer the study assessments in English or Spanish (Table 4) in the families' homes at baseline/enrollment, and after 6 and 18 months of intervention. Home visitors will be trained to gather interim, objectively measured, weight measurements for the purpose of generating more frequent data points, triangulated with the assessment workers' measurements.

2.4.1. Medical and family history.—A thorough family history and physical examination will be conducted at baseline. We will collect demographic data, including socioeconomic status (education, income, eligibility for- and enrollment in SNAP).

2.4.2. Infant growth & waist trajectories.—Weight will be measured on a digital scale (Tanita) accurate to the nearest 5g. Length will be measured to the nearest 0.1 cm using an infanto-meter using the standardized WHO approach, including use of staff training modules. Weight and length will be used to calculate weight-for-length and weight-for-age z-scores (WHO Standards). Infant growth rates will be examined as the change in WLZ, from baseline to follow up (24mo), adjusting for the time between visits. Waist circumference will be measured in triplicate at the umbilicus (nearest 1-mm) using a non-stretch measuring tape.

2.4.3. Infant diet & activity.—To fully capture *infants' diet* (e.g., breastfeeding, use of formula, fruits/ vegetables, fat/sugar intake), we will use multiple tools. *Diet recall.* Mothers will be interviewed about their *infants'* intake of fruits, vegetables, friend foods, and sugared beverages. Mothers will complete the *Infant Feeding Practices Survey II* (IFSQ) [53, 54] to capture breastfeeding and feeding history and introduction to formula and solid foods. *Infants' activity.* Because of validity issues related to accelerometry in infants/young children, we opted to capture time engaged in sedentary activities and structured/unstructured physical activity reported by mothers (e.g., tummy time, watching television, sleeping) [55–57].

2.4.4. Maternal biomarkers for metabolic risks.—Mothers' blood will be drawn by trained assessment workers and plasma will be stored at –80°C for analysis. Biomarkers of obesity and type 2 diabetes risk that will be tested include: blood glucose, lipids, and inflammatory markers (CRP). CRP will be measured using the Millipore Multiple assay kit at the USC DORI Core Laboratory. Lipids will be assayed using Vitros Colorimetric assays (Johnson & Johnson Clinical Dinostics Rochester, NY) for cholesterol, triglycerides and HDL-cholesterol. Sitting blood pressure (mothers) using auscultation and heart rate will be measured on the right arm after a 2-minute rest. Three readings of blood pressure and heart rate will be obtained and the average of the last two last will be recorded.

2.4.5. Maternal weight & waist circumference.—Weight and height will be measured in participants' homes by trained assessment workers, using an electronic scale (Model BWB-800S, Tanita, Portage, MI) and stadiometer (Model PE-AIM-101, Perspective Enterprises) according to standard procedures [58]. Participants will remove shoes, belts, and heavy outerwear and empty pockets. We will measure height in duplicate and if measurements are not within 0.5 cm, we will obtain a third measurement. The mean of all measurements will be used to calculate body mass index (BMI). Waist circumference will be measured at the umbilicus to the nearest 1 mm using a non-stretch measuring tape.

2.4.6. Maternal diet & activity.—Mothers' dietary intake and activities will be assessed using the recall procedure described above with mothers reporting on their own food intake. Outcomes of interest include: servings of fruits/vegetables, fat/sugar intake and sugary-sweetened beverages, and time and frequency that mothers engage in physical activity.

2.4.7. Maternal social networks & support.—Using egocentric social network methods [59] and EgoWeb software [60], we will assess the characteristics of the social actors (people, organizations) and relationships that surround mothers [61, 62]. Using

standard name generator items [62, 63], participants are asked to identify 20 important adults in their lives, and then report on the attributes of each person (demographics, health attributes/behaviors) and types of relationships they share. Relationship characteristics of interest include how they know the person (e.g., family, friend from a community program, etc.), frequency of interaction, provision of support for health behaviors (e.g., encouragement for or co-engagement in specific behaviors), and perceptions of the person's weight status/health behaviors [64–66]. Egocentric network data is used to compute network composition variables (e.g., proportions of family/friends in the network), and variables that represent important network structures (e.g., sparse or dense support). Respondents will also be asked about health-related relationships (e.g., information seeking, support) they have with community organizations. Social network analysis (SNA) will be used to compute summary statistics for each mother's network, such as the proportion of network members that engage in regular exercise or that provide health relevant support, and the density of supportive relationships [67].

2.4.9. Maternal food insecurity.—The U.S. Adult Food Security Survey Module [68] is an 18-item, three-stage design with screeners. Each stage consists of characteristic conditions and experiences of food insufficiency to meet the basic needs of household members, and of the behavioral responses of household members to these conditions. We will test if scores mediate the effect of COPE on infants' outcomes, as energy intake and weight are related to food insecurity [69–77].

2.5. Analytic plan and power analysis

2.5.1. General strategy.—Three waves of data will be collected (baseline/enrollment, 6 and 18 months of intervention). Prior to statistical analyses, data will be carefully inspected to ascertain their quality. We will conduct standard statistical diagnosis and descriptive statistics of demographic and background variables, and examine frequencies for reasonableness, sparseness (categorical data) and non-normality (continuous variables) of the data. Missing data will be addressed using multiple imputation and/or full information maximum likelihood estimation. Psychometric properties of the study scales will be investigated to assure appropriate validity and reliability. Preliminary analyses will be conducted to examine group equivalence on baseline characteristics. Categorical methods of analysis (e.g., cross tabulations, chi-square) will be used for discrete data while *t*-tests will be used for continuous data to test the comparability of the prevention arms. Factors found to be different at baseline will be adjusted for in subsequent analyses. The following covariates will be entered in all analyses: home visitor, home visitor experience (years), number of visits, household composition, race/ethnicity, acculturation, mother's age, medical history/gestational diabetes.

2.5.2. Social network analysis (SNA).—Network data will be analyzed using SNA packages in R (e.g., SNA, igraph) to produce visualizations and statistics that summarize the characteristics of each mothers' network. We will compute the following network statistics: the proportion of network members that provide specific types of health relevant support, and that engage in specific health behaviors; and the density of supportive relationships within each network (i.e., the number of supportive relationships among network members

that are reported, as a proportion of the total number of possible supportive relationships where all network members provide support) [78, 79]. These statistics will be computed for each assessment period (as well as change statistics across periods), and included in the analyses, as described below.

2.5.3. Statistical Models Aims 1-3.—Our conceptual model includes three types of variables: Intervention arms (HVP vs. HVP + obesity prevention) and covariates, mediators, and outcome variables. We will use multiple statistical procedures tied to the analytic objectives of each of our specific aims, including generalized linear modeling, path analysis and structural equation modeling (SEM) approaches. To control for potential cluster effect due to home visitors as families are nested with visitor, statistical models will be developed based on multilevel path analysis to test direct and indirect (or mediational) effects hypothesized in the model [80, 81]. The models involve two levels with mothers or children as Level-1 units and visitors as Level-2 units treated as a random effect. With multilevel path modeling approach, the covariance matrix to be analyzed can be properly decomposed into individual- and group-level covariances to account for the clustering effect due to visitor nesting effect of the data. The multilevel path model can involve all variables from the family level in the analysis. The model can also incorporate distal predictors and mediators from the visitor-level (Level-2) and outcomes from family-level (Level-1) data. The aims of the proposed study focus on the Level-1 units. Following Bentler-Weeks [82] modeling notation, the path model can be expressed as: $\eta = \beta\eta + \gamma\xi$, with all exogenous (distal) variables defined as ξ and all endogenous (mediators and final outcomes) variables as η . The parameters in β and γ matrices can be specified according to the hypotheses of each Aim. Models to be developed are discussed in greater detail below for each Aim. Mplus software [83] will be used for model estimation and evaluation.

2.5.4. Power Analysis Aims 1-3.—A total of 30 home visitors will be recruited and randomized to HVP or HVP + obesity prevention. With an average of 10 families served by each visitor, a total of 300 families will be invited to participate in the proposed study over 18 months. Based on our pilot work and existing HVP data [84–88], we expect a retention rate of 75% of families, which will result in a final sample of more than 200 mothers/infants.

We have calculated power using G*Power [89] based on an effective sample of $N=200$ for the main weight related outcomes with the design of repeated measurement. All tests use a two-sided alpha level of .05. Our pilot study showed a small to medium effect size of .4 (Cohen's d) on our main outcome of children's weight velocity and smaller effect on energy intake after 6 months of intervention. No previous study has investigated the long-term (18 months) delivery of in-home obesity prevention on 0-2-year-old children's growth trajectory, diet and activity. However, an in-home intervention compared to outpatient pediatric counseling resulted in a large effect size of 1.64 (Cohen's d) for changes in zBMI at 12 months, among obese 2-5yo children [90, 91]. After taking inflation factor due to clustering effect of home visitors into account [103], our proposed sample size of 200 will have enough power to detect medium effect sizes based on Cohen's f [92] between .17 and .20.

2.5.5. Real-life economic analysis.—We will document the costs of adding obesity prevention to home visitation services through cost logs and interviews with HVP directors.

We will consider the costs of labor (i.e., the time home visitors spent in training and in administering the obesity prevention curriculum \times their wage rate) and the costs of the materials required for training and for the intervention delivery (i.e., intervention manuals and activity sheets). We will evaluate how these costs can be absorbed through ongoing federal funding allocated to home visitation programs nationwide.

We will further calculate infants and mothers' weight, metabolic, and behavioral trajectories and how they differ by child gender, household structure, and other observables. These analyses will be conducted at two levels. First, we will calculate the cost-effectiveness of delivering obesity prevention as part of HVP (compared to standard HVP curriculum alone) by comparing the cost of adding obesity prevention per unit of improvements in weight, metabolic, or behavioral outcomes with the cost per unit of improvement in these outcomes compared to alternative obesity programs with similar aims (e.g., prevention delivered in outpatient settings). This will provide a measure of the effectiveness of delivering obesity prevention as part of HVP services.

We will rely on an extensive review of the literature to obtain estimates of costs and improvements associated with alternative obesity prevention models delivered in outpatient settings, and their ability to reach ethnically and racially diverse low-income families. Second, in the absence of long-term data, simulation models are often used to predict long-term outcomes and/or evaluate the cost-effectiveness of healthcare interventions. We have developed a simulation model to predict BMI trajectories and associated medical expenditures over the life cycle (e.g., [93]). The model utilizes data from the Medical Expenditure Panel Survey (MEPS) to model yearly changes in BMI and healthcare costs associated with each possible initial BMI state. The model was validated using data from the National Health and Nutrition Examination Survey (NHANES).

3. Discussion

Home visitation programs (HVPs) successfully promote child development and reduce risks of negative psychosocial and academic outcomes [5–23]. Although some HVPs provide basic information on infant nutrition, there has been no comprehensive and sustainable effort to address childhood obesity prevention, nutrition, and physical activity, as part of their services. This represents a critical gap. These children are especially at-risk of obesity, given their families' low level of income. Indeed, the prevalence of high Weight-For-Length among children enrolled in home visitation programs is substantially greater than that of the general U.S. population (based on NHANES data) [94]. To address these disparities, the proposed study tests whether delivering in-home obesity prevention as part of ongoing home visiting services is an effective approach for primary (infants) and secondary (mothers) obesity prevention among low-income, underserved families.

We will identify key maternal and social determinants of the intervention that can be leveraged to prevent childhood obesity in infancy. Our focus on understanding maternal and social determinants of intervention effects increases the significance, innovation, and impact of this research, as follows. First, achieving positive changes in maternal health behaviors and food security is not only beneficial for mothers' health, but may also address the

intergenerational transmission of obesity risk and health disparities. The proposed research represents a unique opportunity to test the impact of key maternal mechanisms on obesity transmission and whether a comprehensive approach to maternal/infant health can alter children's weight trajectories [95]. Second, despite evidence that obesity is influenced by social networks and social-ecological systems, which extend well beyond the parent-child context, few childhood obesity initiatives have translated this evidence into practice. Families are embedded in social networks and in communities that influence their health behaviors and their practices through several mechanisms, in particular via social influence and social support [65, 66, 96–101]. These social factors can ultimately promote or impede behavioral change and maintenance [102–104]. This study is unique in its explicit targeting of families' social networks by creating opportunities for meaningful, health-supportive relationships to improve the adoption and maintenance of healthy behaviors [104, 105].

Akin to other community-based RCTs, this study faces potential challenges. First, illiteracy can interfere with mothers' engagement and adherence to intervention recommendations. The study materials and intervention manual were designed with this issue in mind in developing hands-on demonstrations and practices for families, and group activities for mothers. The intervention material is also rich in pictures with limited need for literacy. Since a large proportion of families are Hispanic, all materials are available in Spanish and English.

Another potential challenge pertains to the synergy between new and existing program content. The obesity curriculum was designed collaboratively with home visitation directors and staff who are experienced in integrating enhancement modules to complement other program goals. In our pilot and formative work, we found no differences between intervention arms on standard home visitation benchmark areas (see Table 2 for a list of benchmark areas targeted by our HVP partner), suggesting that the addition of the obesity module did not negatively affect other program targets.

A third consideration when implementing intervention in the real world relates to treatment fidelity. Intervention fidelity encompasses integrity (interventions are implemented according to established procedures) and differentiation (interventions are distinct from one another).[52] Our preliminary findings suggest that our strategies are effective in preserving integrity and differentiation: (1) We have conducted a comprehensive assessment of the standard HVP curriculum to avoid content overlap. (2) Home visitors complete rigorous training to learn the HVP curriculum and to meet the requirements of Healthy Families America (the HVP model used by our community partner). Home visitors also receive weekly supervision to review progress and address issues. (3) Home visitors delivering the obesity prevention program receive a 2-day initial training and annual refresher courses from Dr. Salvy, with scripted manuals and materials. Dr. Salvy further reviews 25% of the session checklists to monitor fidelity. (4) Weekly supervisions (home visitors) and annual focus groups (families, home visitors, and Community Advisory Board) are conducted to review progress, dosage and timing of delivery, and provide the opportunity to resolve problems or issues encountered. (5) Intervention components are delivered in the home or at specified community-run settings (e.g., group activities), and meetings and supervisions with home

visitors implementing different arms are held on separate days (at Antelope Valley Partners for Health) to minimize the risks of contamination.

3.1. Conclusion

The delivery modalities of current obesity efforts disproportionately restrict reaching and engaging children who are most at-risk for obesity. Extant modalities also limit the development and generalization of healthy habits in the families' home environment. If proven successful, this initiative is poised to have a substantial impact because our proposed strategy can overcome these challenges by building on the strengths of an ongoing infrastructure that provides culturally-tailored and family- and community- oriented services to a segment of the population at high risk for obesity and related diseases. This model of delivery is promising in terms of scalability, sustainability and cost effectiveness (by using existing infrastructure), all of which are critical issues to consider for the delivery of health services. This work has the potential to inform maternal and child health public policy initiatives that seek to address the intergenerational transmission of obesity efforts. If effective, this intervention can be readily disseminated to other HVPs sites nationwide as, over 500 publicly and privately funded home visitation programs provide services to more than 650,000 low-income, underserved children and their families in the U.S. annually.

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References

- [1]. Gonzalez A, MacMillan HL. Preventing child maltreatment: an evidence-based update. *J Postgrad Med.* 2008;54(4):280–6. [PubMed: 18953147]
- [2]. Fergusson DM, Grant H, Horwood LJ, Ridder EM. Randomized trial of the Early Start program of home visitation: parent and family outcomes. *Pediatrics.* 2006;117(3):781–6. [PubMed: 16510658]
- [3]. Matone M, O'Reilly AL, Luan X, Localio R, Rubin DM. Home visitation program effectiveness and the influence of community behavioral norms: a propensity score matched analysis of prenatal smoking cessation. *BMC Public Health.* 2012;12:1016. [PubMed: 23170927]
- [4]. Rubin DM, O'Reilly AL, Luan X, Dai D, Localio AR, Christian CW. Variation in pregnancy outcomes following statewide implementation of a prenatal home visitation program. *Arch Pediatr Adolesc Med.* 2011;165(3):198–204. [PubMed: 21041588]
- [5]. Bilukha O, Hahn RA, Crosby A, Fullilove MT, Liberman A, Moscicki E, et al. The effectiveness of early childhood home visitation in preventing violence: a systematic review. *Am J Prev Med.* 2005;28(2 Suppl 1):11–39. [PubMed: 15698746]
- [6]. Aurelius G, Nordberg L. Home visiting to families with a newborn child. *Scand J Prim Health Care.* 1994;12(2):106–13. [PubMed: 7973188]
- [7]. Barnett B, Duggan AK, Devoe M, Burrell L. The effect of volunteer home visitation for adolescent mothers on parenting and mental health outcomes: a randomized trial. *Arch Pediatr Adolesc Med.* 2002;156(12):1216–22. [PubMed: 12444833]

- [8]. Black MM, Dubowitz H, Krishnakumar A, Starr RH Jr. Early intervention and recovery among children with failure to thrive: follow-up at age 8. *Pediatrics*. 2007;120(1):59–69. [PubMed: 17606562]
- [9]. Daro D, McCurdy K, Falconnier L, Stojanovic D. Sustaining new parents in home visitation services: key participant and program factors. *Child Abuse Negl*. 2003;27(10):1101–25. [PubMed: 14602094]
- [10]. de la Rosa IA, Perry J, Johnson V. Benefits of increased home-visitation services: exploring a case management model. *Fam Community Health*. 2009;32(1):58–75. [PubMed: 19092435]
- [11]. Drummond JE, Weir AE, Kysela GM. Home visitation programs for at-risk young families. A systematic literature review. *Can J Public Health*. 2002;93(2):153–8. [PubMed: 11963523]
- [12]. Holton JK, Harding K. Healthy Families America: ruminations on implementing a home visitation program to prevent child maltreatment. *J Prev Interv Community*. 2007;34(1-2):13–38. [PubMed: 17890192]
- [13]. Izzo CV, Eckenrode JJ, Smith EG, Henderson CR, Cole R, Kitzman H, et al. Reducing the impact of uncontrollable stressful life events through a program of nurse home visitation for new parents. *Prev Sci*. 2005;6(4):269–74. [PubMed: 16075193]
- [14]. Kersten-Alvarez LE, Hosman CM, Riksen-Walraven JM, Van Doesum KT, Hoefnagels C. Long-term effects of a home-visiting intervention for depressed mothers and their infants. *J Child Psychol Psychiatry*. 2010;51(10):1160–70. [PubMed: 20707826]
- [15]. Kitzman HJ, Olds DL, Cole RE, Hanks CA, Anson EA, Arcoleo KJ, et al. Enduring effects of prenatal and infancy home visiting by nurses on children: follow-up of a randomized trial among children at age 12 years. *Arch Pediatr Adolesc Med*. 2010;164(5):412–8. [PubMed: 20439791]
- [16]. Love JM, Kisker EE, Ross C, Raikes H, Constantine J, Boller K, et al. The effectiveness of early head start for 3-year-old children and their parents: lessons for policy and programs. *Dev Psychol*. 2005;41(6):885–901. [PubMed: 16351335]
- [17]. Lyons-Ruth K, Melnick S. Dose-response effect of mother-infant clinical home visiting on aggressive behavior problems in kindergarten. *J Am Acad Child Adolesc Psychiatry*. 2004;43(6):699–707. [PubMed: 15167086]
- [18]. Moss E, Dubois-Comtois K, Cyr C, Tarabulsy GM, St-Laurent D, Bernier A. Efficacy of a home-visiting intervention aimed at improving maternal sensitivity, child attachment, and behavioral outcomes for maltreated children: a randomized control trial. *Dev Psychopathol*. 2011;23(1):195–210. [PubMed: 21262048]
- [19]. Olds DL, Robinson J, O'Brien R, Luckey DW, Pettitt LM, Henderson CR Jr., et al. Home visiting by paraprofessionals and by nurses: a randomized, controlled trial. *Pediatrics*. 2002;110(3):486–96. [PubMed: 12205249]
- [20]. Aitken RJ, Allman-Farinelli MA, King LA, Bauman AE. Current and future costs of cancer, heart disease and stroke attributable to obesity in Australia - a comparison of two birth cohorts. *Asia Pac J Clin Nutr*. 2009;18(1):63–70. [PubMed: 19329397]
- [21]. Thompson DK, Clark MJ, Howland LC, Mueller MR. The Patient Protection and Affordable Care Act of 2010 (PL 111-148): an analysis of maternal-child health home visitation. *Policy Polit Nurs Pract*. 2011;12(3):175–85. [PubMed: 22005527]
- [22]. Tschudy MM, Pak-Gorstein S, Serwint JR. Home visitation by pediatric residents - perspectives from two pediatric training programs. *Acad Pediatr*. 2012;12(5):370–4. [PubMed: 22999355]
- [23]. Wagner MM, Clayton SL. The Parents as Teachers program: results from two demonstrations. *Future Child*. 1999;9(1):91–115, 79–89. [PubMed: 10414012]
- [24]. Centers for Disease C, Prevention. Obesity prevalence among low-income, preschool-aged children--New York City and Los Angeles County, 2003-2011. *MMWR Morb Mortal Wkly Rep*. 2013;62(2):17–22. [PubMed: 23325351]
- [25]. Weedn AE, Ang SC, Zeman CL, Darden PM. Obesity prevalence in low-income preschool children in Oklahoma. *Clin Pediatr (Phila)*. 2012;51(10):917–22. [PubMed: 22523274]
- [26]. Pan L, Blanck HM, Sherry B, Dalenius K, Grummer-Strawn LM. Trends in the prevalence of extreme obesity among US preschool-aged children living in low-income families, 1998-2010. *JAMA*. 2012;308(24):2563–5. [PubMed: 23268509]

- [27]. Centers for Disease C, Prevention. Obesity prevalence among low-income, preschool-aged children - United States, 1998-2008. *MMWR Morb Mortal Wkly Rep.* 2009;58(28):769-73. [PubMed: 19629026]
- [28]. Birch LL, Davison KK. Family environmental factors influencing the developing behavioral controls of food intake and childhood overweight. *Pediatr Clin North Am.* 2001 ;48(4):893-907. [PubMed: 11494642]
- [29]. Birch LL. Development of Food Preferences. *Annual Review of Nutrition.* 1999;19:41-62.
- [30]. Hughes CC, Sherman SN, Whitaker RC. How low-income mothers with overweight preschool children make sense of obesity. *Qual Health Res.* 2010;20(4):465-78. [PubMed: 20147505]
- [31]. Hurley KM, Cross MB, Hughes SO. A systematic review of responsive feeding and child obesity in high-income countries. *J Nutr.* 2011;141(3):495-501. [PubMed: 21270360]
- [32]. Schulz KF, Altman DG, Moher D, Group C. CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. *Annals of internal medicine.* 2010;152(11):726-32. [PubMed: 20335313]
- [33]. Ebbeling CB, Feldman HA, Chomitz VR, Antonelli TA, Gortmaker SL, Osganian SK, et al. A randomized trial of sugar-sweetened beverages and adolescent body weight. *N Engl J Med.* 2012;367(15):1407-16. [PubMed: 22998339]
- [34]. Ebbeling CB, Feldman HA, Osganian SK, Chomitz VR, Ellenbogen SJ, Ludwig DS. Effects of decreasing sugar-sweetened beverage consumption on body weight in adolescents: a randomized, controlled pilot study. *Pediatrics.* 2006;117(3):673-80. [PubMed: 16510646]
- [35]. Wang YC, Ludwig DS, Sonnevile K, Gortmaker SL. Impact of change in sweetened caloric beverage consumption on energy intake among children and adolescents. *Arch Pediatr Adolesc Med.* 2009;163(4):336-43. [PubMed: 19349562]
- [36]. Ludwig DS, Peterson KE, Gortmaker SL. Relation between consumption of sugar-sweetened drinks and childhood obesity: a prospective, observational analysis. *Lancet.* 2001 ;357(9255):505-8. [PubMed: 11229668]
- [37]. Kaplowitz GJ. An update on the dangers of soda pop. *Dent Assist.* 2011;80(4):14-6, 8-20, 2-3 passim; quiz 9-31.
- [38]. Spitzer L, Rodin J. Effects of fructose and glucose preloads on subsequent food intake. *Appetite.* 1987;8(2):135-45. [PubMed: 3592650]
- [39]. Wesnes KA, Pincock C, Richardson D, Helm G, Hails S. Breakfast reduces declines in attention and memory over the morning in schoolchildren. *Appetite.* 2003;41(3):329-31. [PubMed: 14637332]
- [40]. Birch LL, Doub AE. Learning to eat: birth to age 2 y. *Am J Clin Nutr.* 2014;99(3):723S-8S. [PubMed: 24452235]
- [41]. Institute of Medicine (IOM). Early Childhood Obesity Prevention Policies. Washington, DC: The National Academies Press; 2011.
- [42]. Paul IM, Williams JS, Anzman-Frasca S, Beiler JS, Makova KD, Marini ME, et al. The Intervention Nurses Start Infants Growing on Healthy Trajectories (INSIGHT) study. *BMC Pediatr.* 2014;14:184. [PubMed: 25037579]
- [43]. Raiten DJ, Raghavan R, Porter A, Obbagy JE, Spahn JM. Executive summary: Evaluating the evidence base to support the inclusion of infants and children from birth to 24 mo of age in the Dietary Guidelines for Americans--"the B-24 Project". *Am J Clin Nutr.* 2014;99(3):663S-91S. [PubMed: 24500158]
- [44]. Pliner P, Salvy SJ. Food neophobia in humans. In: Shepherd R, Raats M, editors. *Psychology of Food Choice*: CABI Publishing; 2006.
- [45]. Sullivan SA, Birch LL. Pass the sugar, pass the salt: Experience dictates preference. *Developmental Psychology.* 1990;26(4):546-51.
- [46]. Wardle J, Cooke LJ, Gibson EL, Sapochnik M, Sheiham A, Lawson M. Increasing children's acceptance of vegetables; a randomized trial of parent-led exposure. *Appetite.* 2003;40(2):155-62. [PubMed: 12781165]
- [47]. Agras WS, Hammer LD, McNicholas F, Kraemer HC. Risk factors for childhood overweight: a prospective study from birth to 9.5 years. *J Pediatr.* 2004;145(1):20-5. [PubMed: 15238901]

- [48]. Linscheid TR. Behavioral treatments for pediatric feeding disorders. *Behav Modif.* 2006;30(1):6–23. [PubMed: 16332643]
- [49]. United States Department of Agriculture. “How Much Physical Activity Is Needed?” Web2015 [Available from: <http://choosemyplate.gov/physical-activity/amount.html>].
- [50]. Barlow SE. Expert committee recommendations regarding the prevention, assessment, and treatment of child and adolescent overweight and obesity: summary report. *Pediatrics.* 2007;120 (Suppl 4):s164–92. [PubMed: 18055651]
- [51]. U.S Department of Agriculture NIFA Program Leadership. Expanded Food and Nutrition Education Program Policies <http://www.nifa.usda.gov/nea/food/efnep/pdf/program-policy.pdf>2013 [Available from: <http://www.nifa.usda.gov/nea/food/efnep/pdf/program-policy.pdf>].
- [52]. Moncher FJ, Prinz RJ. Treatment fidelity in outcome studies. *Clinical Psychology Review.* 1991;11:247–66.
- [53]. Fein SB, Labiner-Wolfe J, Shealy KR, Li R, Chen J, Grummer-Strawn LM. Infant Feeding Practices Study II: study methods. *Pediatrics.* 2008;122 Suppl 2:S28–35. [PubMed: 18829828]
- [54]. Fein SB, Li R, Chen J, Scanlon KS, Grummer-Strawn LM. Methods for the year 6 follow-up study of children in the Infant Feeding Practices Study II. *Pediatrics.* 2014;134 Suppl 1:S4–S12. [PubMed: 25183754]
- [55]. Booth MJ, Okely AD, Chey T, Bauman A. The reliability and validity of the Adolescent Physical Activity Recall Questionnaire. *Medicine and Science in Sports and Exercise.* 2002;34(12):1986–95. [PubMed: 12471306]
- [56]. Gross LD, Sallis JF, Buono MJ, Roby JJ, Nelson JA. Reliability of interviewers using the Seven-Day Physical Activity Recall. *Res Q Exerc Sport.* 1990;61(4):321–5. [PubMed: 2132889]
- [57]. Timperio A, Salmon J, Crawford D. Validity and reliability of a physical activity recall instrument among overweight and non-overweight men and women. *J Sci Med Sport.* 2003;6(4):477–91. [PubMed: 14723397]
- [58]. Lohman TG, Roche AF, Martorell R. Anthropometric Standardization Reference Manual. Lohman TG, Roche AF, Martorell R, editors. Champaign, IL: Human Kinetics Book; 1988.
- [59]. Carrington PJ, Scott J, Wasserman S. Models and Methods in Social Network Analysis. New York, NY: Cambridge University Press; 2006.
- [60]. EgoWeb 2.0. In: <http://github.com/qualintitative/egoweb>, editor. Computer Software.
- [61]. McCarty C Structure in personal networks. *Journal of Social Structure.* 2002;3:20.
- [62]. McCarty C, Killworth PD, Rennell J. Impact of methods for reducing respondent burden on personal network structural measures. *Social Networks* 2007;29:300–15.
- [63]. Marsden P Recent Developments in Network Measurement Ω. In: Carrington PJ, Scott J, Wasserman S, editors. Models and Methods in Social Network Analysis: Cambridge University Press; 2005 p. 8–30.
- [64]. de la Haye K, de Heer HD, Wilkinson AV, Koehly LM. Predictors of parent-child relationships that support physical activity in Mexican-American families. *J Behav Med.* 2014;37(2):234–44. [PubMed: 23203139]
- [65]. Ashida S, Wilkinson AV, Koehly LM. Social influence and motivation to change health behaviors among Mexican-origin adults: implications for diet and physical activity. *Am J Health Promot.* 2012;26(3): 176–9. [PubMed: 22208416]
- [66]. Ashida S, Hadley DW, Goergen AF, Skapinsky KF, Devlin HC, Koehly LM. The importance of older family members in providing social resources and promoting cancer screening in families with a hereditary cancer syndrome. *Gerontologist.* 2011;51(6):833–42. [PubMed: 21562055]
- [67]. Wasserman S, Faust K. Social Network Analysis: Methods and Applications: Cambridge University Press; 1994.
- [68]. Bickel G, Nord M, Price C, Hamilton W, Cook J. Guide to measuring household food security. [http://www.fns.usda.gov/fsec/FILES/Guide%20to%20Measuring%20Household%20Food%20Security\(3-23-00\).pdf](http://www.fns.usda.gov/fsec/FILES/Guide%20to%20Measuring%20Household%20Food%20Security(3-23-00).pdf): USDA; 2000.
- [69]. Bernal J, Frongillo EA, Herrera H, Rivera J. Children live, feel, and respond to experiences of food insecurity that compromise their development and weight status in periurban Venezuela. *J Nutr.* 2012; 142(7): 1343–9. [PubMed: 22623397]

- [70]. Larson NI, Story MT. Food insecurity and weight status among U.S. children and families: a review of the literature. *Am J Prev Med.* 2011;40(2): 166–73. [PubMed: 21238865]
- [71]. Kaur J, Lamb MM, Ogden CL. The Association between Food Insecurity and Obesity in Children-The National Health and Nutrition Examination Survey. *J Acad Nutr Diet.* 2015;115(5):751–8. [PubMed: 25737437]
- [72]. Schluskel MM, Silva AA, Perez-Escamilla R, Kac G. Household food insecurity and excess weight/obesity among Brazilian women and children: a life-course approach. *Cad Saude Publica.* 2013;29(2):219–26. [PubMed: 23459802]
- [73]. Metallinos-Katsaras E, Must A, Gorman K. A longitudinal study of food insecurity on obesity in preschool children. *J Acad Nutr Diet.* 2012;112(12):1949–58. [PubMed: 23174682]
- [74]. Martin MA, Lippert AM. Feeding her children, but risking her health: the intersection of gender, household food insecurity and obesity. *SocSci Med.* 2012;74(11):1754–64.
- [75]. Eisenmann JC, Gundersen C, Lohman BJ, Garasky S, Stewart SD. Is food insecurity related to overweight and obesity in children and adolescents? A summary of studies, 1995-2009. *Obes Rev.* 2011;12(5):e73–83. [PubMed: 21382151]
- [76]. Buscemi J, Beech BM, Relyea G. Predictors of obesity in Latino children: acculturation as a moderator of the relationship between food insecurity and body mass index percentile. *J Immigr Minor Health.* 2011;13(1):149–54. [PubMed: 19472054]
- [77]. Meyers AF, Karp RJ, Krai JG. Poverty, food insecurity, and obesity in children. *Pediatrics.* 2006;118(5):2265–6.
- [78]. Crossley N, et al. *Social Network Analysis for Ego-Nets: Social Network Analysis for Actor-Centred Networks*: SAGE; 2015.
- [79]. Wasserman S, Faust K. *Social Network Analysis: Methods and Applications*. Cambridge: UK: Cambridge University Press; 1994.
- [80]. Pituch KA, Stapleton LM, Kang JY. A comparison of single sample and bootstrap methods to assess mediation in cluster randomized trials. *Multivariate Behavioral Research.* 2006;41:367–400. [PubMed: 26750340]
- [81]. Preacher KJ, Zyphur MJ, Zhang Z. A general multilevel SEM framework for assessing multilevel mediation. *Psychological Methods.* 2010;15:209–33. [PubMed: 20822249]
- [82]. Bentler PM, Weeks DG. Linear structural equations with latent variables. *Psychometrika.* 1980;45:289–308.
- [83]. Muthen LK, Muthen BO. *Mplus User's Guide Seventh Edition*. Los Angeles, CA: Muthen & Muthen; 2012.
- [84]. Harding K, Galano J, Martin J, Huntington L, Schellenbach CJ. Healthy Families America effectiveness: a comprehensive review of outcomes. *J Prev Interv Community.* 2007;34(1-2): 149–79. [PubMed: 17890198]
- [85]. DuMont K, Mitchell-Herzfeld S, Greene R, Lee E, Lowenfels A, Rodriguez M, et al. Healthy Families New York (HFNY) randomized trial: effects on early child abuse and neglect. *Child Abuse Negl.* 2008;32(3):295–315. [PubMed: 18377991]
- [86]. Lee E, Mitchell-Herzfeld SD, Lowenfels AA, Greene R, Dorabawila V, DuMont KA. Reducing low birth weight through home visitation: a randomized controlled trial. *Am J Prev Med.* 2009;36(2): 154–60. [PubMed: 19135906]
- [87]. Sackoff J, Schwarz AG, Senter L. Reducing low birth weight through home visitation. *Am J Prev Med.* 2009;37(5):472; author reply -3. [PubMed: 19840705]
- [88]. Hoagwood KE, Olin SS, Horwitz S, McKay M, Cleek A, Gleacher A, et al. Scaling up Evidence-Based Practices for Children and Families in New York State: Toward Evidence-Based Policies on Implementation for State Mental Health Systems. *J Clin Child Adolesc Psychol.* 2014.
- [89]. Faul F, Erdfelder E, Lang A, Buchner D. G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behavior Research Methods.* 2007;39:175–91. [PubMed: 17695343]
- [90]. Stark LJ, Spear S, Boles R, Kuhl E, Ratcliff M, Scharf C, et al. A pilot randomized controlled trial of a clinic and home-based behavioral intervention to decrease obesity in preschoolers. *Obesity (Silver Spring).* 2011;19(1):134–41. [PubMed: 20395948]

- [91]. Stark LJ, Clifford LM, Towner EK, Filigno SS, Zion C, Bolling C, et al. A pilot randomized controlled trial of a behavioral family-based intervention with and without home visits to decrease obesity in preschoolers. *J Pediatr Psychol*. 2014;39(9): 1001–12. [PubMed: 25080605]
- [92]. Cohen J Statistical power analysis for the behavioral sciences (2nd ed.). Hillsdale, NJ: Lawrence Earlbaum Associates; 1988.
- [93]. Gaudette E, Goldman DP, Messali A, Sood N. Do Statins Reduce the Health and Health Care Costs of Obesity? *Pharmacoeconomics*. 2015;33(7):723–34. [PubMed: 25576147]
- [94]. Thorland W, Currie D, Colangelo C. Status of High Body Weight Among Nurse-Family Partnership Children. *MCN Am J Matern Child Nurs*. 2017;42(6):352–7. [PubMed: 29049059]
- [95]. Committee on Accelerating Progress in Obesity Prevention Institute of Medicine. Accelerating Progress in Obesity Prevention: Solving the Weight of the Nation. 2012.
- [96]. Ayala GX, Baquero B, Arredondo EM, Campbell N, Larios S, Elder JP. Association between family variables and Mexican American children's dietary behaviors. *Journal of nutrition education and behavior*. 2007;39(2):62–9. [PubMed: 17346653]
- [97]. Bauer KW, Neumark-Sztainer D, Fulkerson JA, Hannan PJ, Story M. Familial correlates of adolescent girls' physical activity, television use, dietary intake, weight, and body composition. *Int J Behav Nutr Phys Act*. 2011 ;8:25. [PubMed: 21453516]
- [98]. Bauer KW, Laska MN, Fulkerson JA, Neumark-Sztainer D. Longitudinal and secular trends in parental encouragement for healthy eating, physical activity, and dieting throughout the adolescent years. *J Adolesc Health*. 2011;49(3):306–11. [PubMed: 21856524]
- [99]. Gorin AA, Wing RR, Fava JL, Jakicic JM, Jeffery R, West DS, et al. Weight loss treatment influences untreated spouses and the home environment: evidence of a ripple effect. *Int J Obes (Lond)*. 2008;32(11):1678–84. [PubMed: 18762804]
- [100]. Pachucki MA, Jacques PF, Christakis NA. Social Network Concordance in Food Choice Among Spouses, Friends, and Siblings. *American Journal of Public Health*. 2011;AJPH.2011.300282.
- [101]. Patrick H, Nicklas TA. A review of family and social determinants of children's eating patterns and diet quality. *J Am Coll Nutr*. 2005;24(2):83–92. [PubMed: 15798074]
- [102]. Valente TW. *Social Networks and Health. Models, Methods, and Applications*. New York: Oxford University Press; 2010.
- [103]. Valente TW, Fosados R. Diffusion of innovations and network segmentation: the part played by people in promoting health. *Sex Transm Dis*. 2006;33(7 Suppl):S23–31. [PubMed: 16794552]
- [104]. Valente TW. Network interventions. *Science*. 2012;337(6090):49–53. [PubMed: 22767921]
- [105]. Gest SD, Osgood DW, Feinberg ME, Bierman KL, Moody J. Strengthening prevention program theories and evaluations: contributions from social network analysis. *Prev Sci*. 2011;12(4):349–60. [PubMed: 21728069]

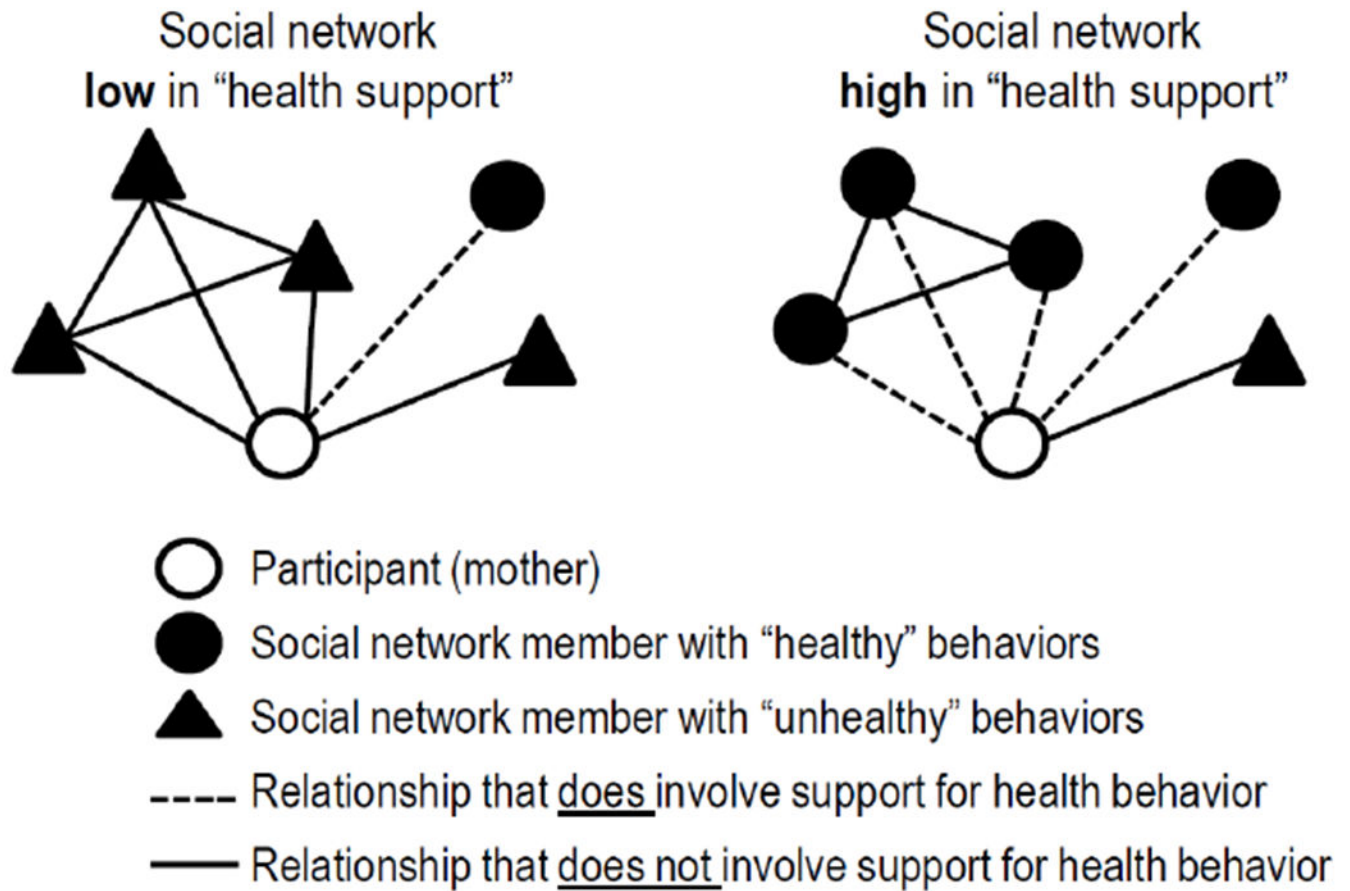


Figure 1.
Social network characteristics relevant to healthy behavior change

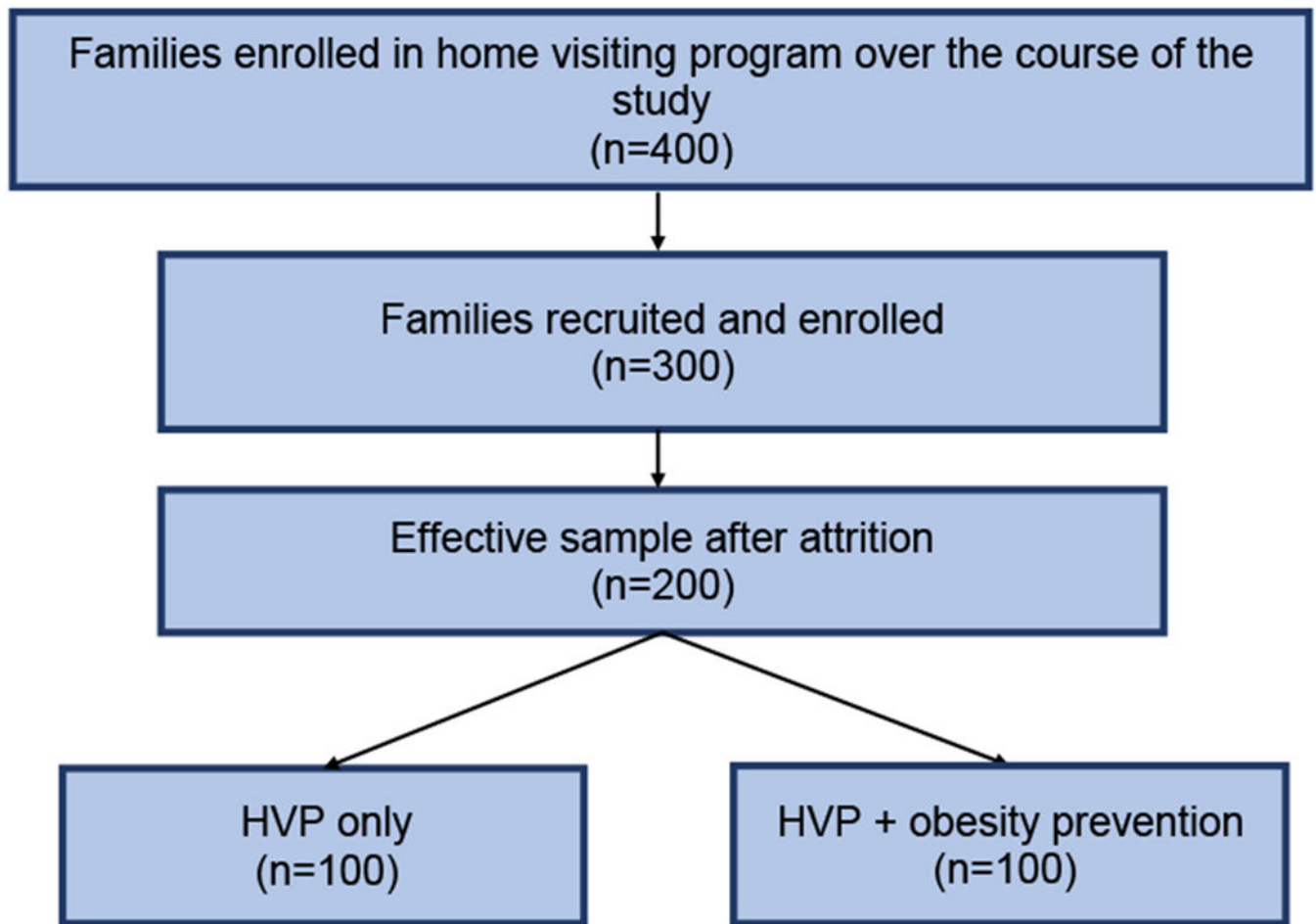


Figure 2.
CONSORT Flow diagram (projected)

Table 1.

Logic model for the delivery of obesity prevention as part of home visitation programs.

SITUATION: More than 40% of low-income children enrolled in federally funded programs are overweight or obese by age 5. Obesity efforts have limited impact among underserved, low-income children, at risk for obesity.		
INPUTS	OUTPUTS	OUTCOMES
<ul style="list-style-type: none"> Existing home visitation infrastructure Funding Evidence-based nutrition, activity, and behavioral components; Research and education expertise; Pilot study evidence Partnership (academia, service systems, stakeholders, families, community organizations) Community Advisory Board (CAB) Training and intervention curricula Input from childhood obesity experts 	<p>ACTIVITIES</p> <ul style="list-style-type: none"> Delivery of an obesity prevention curriculum: nutrition, physical activity, psychosocial support and behavioral change, healthy home environment, support and community connectedness, social-experiential activities <p>PARTICIPANTS</p> <ul style="list-style-type: none"> Mothers/infants receiving home visitation services Home visitors, directors and stakeholders 	<p>SHORT AND MEDIUM TERM</p> <ul style="list-style-type: none"> Healthier infant feeding practices Healthier home environment Healthier diet and physical activity for mothers and infants Social connections supporting health <p>LONG-TERM</p> <ul style="list-style-type: none"> Lowered obesity incidence and health disparities among children involved in home visitation programs Reduced costs of obesity and related diseases
<p>ASSUMPTIONS</p> <ul style="list-style-type: none"> Personal, family and structural factors influence the outcomes of childhood obesity prevention. The home visitation program infrastructure provides a scalable, sustainable, cost-efficient delivery model for obesity prevention. Combining didactic and social experiential learning is necessary to engage and mobilize families and children. Supportive social networks are pivotal to sustain healthy change 		<p>EXTERNAL FACTORS</p> <ul style="list-style-type: none"> Underserved families lack access to opportunities and resources that facilitate healthy behaviors (e.g., poverty, food deserts). Social and community contexts can support or create barriers to healthy behaviors. Home visitation programs do not currently address childhood obesity, and home visitors are not trained to address obesity risks.
<p>EVALUATION AND OUTCOMES: <i>Aim 1</i> (maternal and infant outcomes). Test the direct effects of obesity prevention on infants and mothers' weight, metabolic and behavioral trajectories. <i>Aim 2</i> (maternal transmission). Test the hypothesis that mothers' weight, diet and behavioral outcomes (activity, feeding practices, and food insecurity) mediate the effect of obesity prevention on infants' outcomes. <i>Aim 3 (social transmission)</i>. <i>Aim 3a</i> tests the direct effect of obesity prevention on maternal networks. <i>Aim 3b</i> tests whether the characteristics of maternal networks mediate maternal and infant outcomes. <i>Secondary Aim</i>. Conduct a real-life economic analysis (costs, cost-savings and non-monetary benefits) of integrating obesity prevention into existing a home visitation program.</p>		

Table 2.

Components of the two intervention arms compared.

	HVP curriculum	HVP curriculum + obesity prevention
Maternal/infant health	×	×
Child physical and social development	×	×
Crime and domestic violence	×	×
Child abuse and neglect	×	×
Family economic stability	×	×
Breastfeeding	×	×
Maternal nutrition		×
Infant nutrition and feeding practices		×
Maternal and child physical activity and play		×

Table 3.

Key components of the obesity prevention curriculum

Components	Content
Maternal nutrition	Home visitors coach mothers to gradually build healthier nutrition goals congruent to their cultural practices and ethnic specific food palate: (a) increasing intake of vegetables and fruits (5 servings/day of fruits and vegetables) and integrating nutrient-dense ingredients in their families' meals/recipes; (b) limiting intake of high-saturated fat and sugar in modifying families' favorite recipes; (c) eliminating sugar-sweetened beverage intake, supported by the provision of information and activities on sugar content, long-term effects of high sugar consumption, importance of drinking water, and impact of advertising [33–39]; (d) Home visitors teach mothers to prepare and store foods they can afford, and/or receive from <i>WIC</i> and the <i>Food Bank</i> , to meet these healthy eating goals.
Infants and young children nutrition	Mothers learn about feeding/eating developmental stages and transitions, and healthy feeding [40–43] practices to promote: (a) responsiveness to child hunger and fullness cues; (b) the consumption of nutrient-dense foods (as opposed to energy-dense); (c) the transition to a structured schedule for meals/snacks from complementary feeding; and (d) the use of non-food related child soothing techniques. Mothers also learn strategies to address neophobia [44, 45], such as repeated multi-sensory (i.e., smell, touch, taste) exposures to nutrient-dense novel foods [46], gradual texture shaping, parents/caregivers modeling, and involvement of children in food selection and preparation; and strategies to handle meal-related tantrums (e.g., redirection, positive reinforcement of appropriate behaviors) [47, 48].
Maternal and child physical activity	Although there is no unequivocally accepted guideline for the number of minutes children 0-2yo should be active each day [49], the DHHS has summarized recommendations from the National Association for Sport and Physical Education, the American College of Sports Medicine, and the National Institutes of Health: (a) daily planned physical activities, including tummy time, that safely support the infant's developmental milestones (e.g. head and neck self-support, rolling, floor sitting, kicking, crawling, reaching and grasping for objects, etc.); (b) engage in 30 minutes of supervised but <i>unstructured</i> physical activity each day; and (c) avoid being sedentary for more than 60 minutes at a time, except when sleeping. The American Academy of Pediatrics (A.A.P.) Expert Committee further suggests limiting screen time [50]. Our obesity prevention module is premised on the above guidelines in addition to CDC guidelines for adults (150 minutes of moderate intensity physical activity/week). Parents learn to make activity/play a daily habit for their entire family by exploiting lifestyle activities (e.g., taking the stairs, walking to the shop). Home visitors help parents design activities around their local environment, schedule, and preferences, and to optimize their use of safe spaces. Parents are provided with information about resources and free group activities conducive to physical activity (e.g., parks, walking clubs, outings, etc.), and classes they can take with their children and with other HVP families. The curriculum emphasizes the importance of parents co-engaging in activities with their children to set a good example through modeling and to provide opportunities for their children to be physically active.

Table 4.

Assessment time points (month of intervention) and key measures.

	Baseline	3	6	9	12	15	18
Covariates							
Race/ethnicity, household composition, post-partum depression, maternal age, medical history (including preeclampsia/gestational diabetes)	×						
Mothers							
Height/weight and waist circumference	×	×	×	×	×	×	×
Blood, blood pressure, heart rate	×						×
Diet and activity recall	×		×				×
Feeding practices	×		×				×
Food insecurity	×		×				×
Social support and social networks	×		×				×
Infants							
Weight/length and waist circumference	×	×	×	×	×	×	×
Blood (heel prick)	×						×
Diet and activity recall (mother report)	×		×				×
Cost Analysis							
Costs of labor and costs of materials	×		×		×		×